UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

DECISION DOCUMENT

SUBJECT: Copper Octanoate; Tolerance Exemption; Registration of New Chemical

FROM: James J. Jones, Acting Director
Registration Division (7505C)

TO: Daniel M. Barolo, Director
Office of Pesticide Programs (7501C)

BACKGROUND

On May 15, 1996 W. Neudorff GmbH KG submitted a petition for exemption from the requirement for a tolerance for residues of copper octanoate when used in accordance with good agricultural practice as an active ingredient in pesticide formulations applied to growing crops. On March 4, 1996 the same company submitted registration applications for two products: NEU1140F Copper Soap and NEU1140F RTU Copper Soap.

Adequate product chemistry, toxicology, residue chemistry, environmental fate and ecological effects data have been submitted and reviewed to support a tolerance exemption and registration as a new chemical.

SCIENTIFIC FINDINGS

Toxicological Characteristics

Copper octanoate is classified category III [CAUTION] for acute oral, dermal and inhalation toxicity; and category IV for eye and skin irritation. The dermal sensitization studies were negative.

There is adequate information available to characterize the toxicity of the copper ion. Copper is ubiquitous in nature and is a necessary nutritional element for both animals and plants. It is one of 26 elements found essential to life. The copper ion is present in the adult human body at levels of 80-150 milligram. Oral ingestion of excessive amounts of the copper ion from pesticidal uses is unlikely; copper compounds are irritating to the gastric mucosa and emesis usually occurs promptly, thereby reducing the amount of copper ion available for absorption into

the human body. Only a small percentage of copper ingested is absorbed, and most the absorbed copper is excreted. In view of the facts that the copper ion occurs naturally in most foods and the metabolism of copper is well understood, there is no reason to expect that long-term exposure to copper ion in the diet is likely to pose the risk of chronic or sub-chronic adverse effects.

As part of the hazard assessment process, the Agency reviews the available toxicological database to determine the endpoints of concern for acute and chronic dietary exposure; and short, intermediate and chronic term occupational and residential exposure. In the case of copper octanoate the Agency only reviewed acute toxicity data on the end-use product formulations, since information currently available to the Agency indicates that there is no significant toxicity from exposure to copper octanoate that lasts from one day to several months. The Agency has exempted from the requirement of a tolerance other similar compounds to copper octanoate, such as the, copper salts of fatty acids that include: copper oleate, copper lineolate and copper acetate which are listed in 40 CFR 1011 (b)(1). Therefore, no risk assessments are required for any exposure scenarios.

After taking into account the factors set forth in section 408(b)(2)(D), EPA concludes that copper does not present a dietary risk under reasonably forseeable circumstances. Accordingly, EPA concludes that there is a reasonable certainty that no harm will result to consumers, including infants and children, from aggregate exposure to copper. Because copper has no significant toxicity EPA has not assessed its risk using a margin of safety approach and, therefore, the requirement pertaining to an additional safety factor for infants and children is not applicable to EPA's safety determination for this exemption.

Environmental Fate

Copper octanoate degrades to form free copper and the organic ligand octanoic acid. The free cooper and native copper are indistinguishable and behave similarly in the natural copper cycle. The organic ligand, octanoic acid, is expected to degrade through microbially mediated processes. Background copper concentrations can range from 1 to 10 ppb in non-polluted natural water, 10-60 ppb in soil pore water and 2-100 ppm in soils. Since copper does not degrade, repeated use of copper pesticides will increase the total copper concentration in soil. Environmental availability of copper is predominantly controlled by sorption to soil and sediments. Partitioning coefficients of copper range from 100 to 100,000 L/Kg in soil and sediment, indicating very high binding affinities.

Ecological Effects

It is unlikely that copper octanoate would cause significantly different fish and wildlife effects than the numerous other copper compounds which are already exempted from the requirement of a tolerance.

OCCUPATIONAL EXPOSURE

It is unlikely that the occupational exposure risk for copper octanoate would differ significantly from the numerous other copper compounds which are already exempted from the requirement of a tolerance.

RECOMMENDATION

I recommend that you concur with the exemption from the requirement of a tolerance by adding and alphabetically inserting cooper octanoate in 40 CFR 180.1001 (b)(1); and the registration of this new active ingredient under FIFRA section 3(c)(5).

CONCUR: _____

DO NOT CONCUR: _____

DATE: 7/24/97